

### **REMARKS**

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

#### **I. Status of the claims**

Claims 3, 6, 15, 22 and 23 were previously cancelled. Claims 2, 8-14, 16-21, and 24-29 are withdrawn. Applicant respectfully requests entry and consideration of the withdrawn subject matter upon the identification of allowable subject matter in the generic or linking claims.

Claim 1 is cancelled. Claim 4, which previously depended from claim 1, is amended to incorporate elements from claim 1, and is now independent. Claims 5 and 7 previously depended from claim 1 and have been amended to depend from claim 4. No new matter is added. Upon entry of the foregoing, claims 4, 5 and 7 are under examination.

#### **II. Information Disclosure Statement**

Justifying the lining through of a citation on form PTO/SB/08, the Office Action asserts that reference Cite No. F7, cited in the Information Disclosure Statement of August 26, 2011, was not provided to the Office. Contrary to the assertion of the Office, the single page F7 was submitted, and is visible on PAIR, but appears to be scanned as the last page of the previous non-patent literature document. Applicant respectfully requests that the Examiner review F7 and return an initialed copy of the relevant PTO/SB/08, indicating that F7 has been considered.

#### **III. Novelty under 35 U.S.C. § 102**

At page 3 of the Action, the Examiner rejects claims 1, 4, and 5 as allegedly anticipated under 35 U.S.C. § 102(b) over Aoyagi et al., "Methods for detecting or assaying virus," EP 0 967 484 (EP '484). Page 3 of the Action asserts:

Aoyagi teaches a method of treating a sample comprising HCV; see abstract and at least para. [0002]. The method comprises treating the sample with an acidifying agent, . . . in combination with a cationic surfactant having a straight chain alkyl group of

10 or more carbon atoms and a tertiary amine or a quaternary ammonium salt in the same molecule; see abstract, para. [0080] and [0091]. . . Because Aoyagi describes the same step(s) using the same composition, the same results must occur as instantly claimed

Applicant respectfully traverses the rejection because it is based on a misreading of EP '484. The Examiner is citing to two separate sections of EP '484, relating to different steps, with different reagents.

Paragraph [0080] is part of a section directed to removing hemoglobin and antibodies binding to the virus (paragraphs [0068]-[0071]). Paragraph [0077] describes how treatment with acid or alkali can inactivate antibodies, but has limitations. Paragraph [0078] describes treatment with acid and guanidine, and how it can be improved by the addition of surfactants. Paragraph [0079] describes the suitable surfactants as nonionic, amphoteric or anionic. Paragraph [0080] describes treatment guanidium hydrochloride and *nonionic* surfactants (Tween and Triton X-100). **Nowhere are described *cationic* surfactants.**

Paragraph [0091] is part of a section titled "exposure of virus antigen" (paragraphs [0082]-[0092]), and is distinguished from the previous section in that it does not use acidifying agents. Acidifying agents are not used because this section "relates to a method of detecting the virus antigen in a sample collected during the window period, antibody to the virus antigen has not been formed yet and so the disruption of the virus particle to expose the virus antigen is sufficient and there is no need to destroy antibodies present in the sample." (paragraph [0082]). Paragraphs [0088]-[0090] describe suitable surfactants, such as cationic surfactants. Paragraph [0091] states that "two types of surfactants may be used," but **nowhere does it say that the surfactants may be used with an acidifying agent.**

EP '484 describes *separate steps with separate treating agents for separate purposes*, and does not describe their combination. Thus, EP '484 does not describe a method of treating an HCV-containing sample with a treating agent containing: (a) an acidifying agent, and (b) a cationic surfactant having both a straight chain alkyl group of 10 or more carbon atoms and a tertiary amine or a quaternary ammonium salt in the same molecule, as claimed. Applicant has found that this combination of reagents denatures antibodies, the viral

envelope, and the viral core to expose the antigens, and is readily reversible by neutralization for a subsequent detection step with a probe.

The following table illustrates the differences between the separate treating agents for separate purposes in EP '484 and the present invention's disclosure of a single, novel, treating agent for both purposes.

Action of Treating agent	Present invention combination of treating agents	Aoyagi reference combination of treating agents
Release (exposure) of antigen	# Acidifying agent; and # Cationic surfactant having both a straight chain alkyl group of 10 or more carbon atoms and a tertiary amine or quaternary ammonium in the same molecule	# Cationic surfactant having both a straight chain alkyl group of 10 or more carbon atoms and a secondary amine, tertiary amine, or quaternary ammonium in the same molecule See the specification [0090]-[0091]
Decomposition of antibodies	# Acidifying agent; and # Cationic surfactant having both a straight chain alkyl group of 10 or more carbon atoms and a tertiary amine or quaternary ammonium in the same molecule	# Acidifying agent; # Guanidine; and # Amphoteric surfactant, or nonionic surfactant See the specification [0078]-[0081]

Because EP '484 does not disclose all elements of the presently claimed invention, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. § 102(b).

Moreover, EP '484 does not render obvious pending claims 4, 5 and 7. Not only does EP '484 fail to teach all elements required for a *prima facie* case of obviousness under 35 U.S.C. § 103, but even if such a case had been established, the claimed invention shows unexpected results. The sensitivity of HCV detection was markedly enhanced by a combination of (a) an acidifying agent, and (b) a cationic surfactant having both a straight chain alkyl group of 10 or more carbon atoms and a tertiary amine or a quaternary ammonium salt in the same molecule. Such enhancement was not seen with acid alone, or acid and

anionic or nonionic surfactants (*see* page 24 of the Application), nor expected based on theory. Accordingly, the claims are not obvious.

**IV. Obviousness under 35 U.S.C. § 103**

Claim 7 is rejected over EP '484 in view of U.S. Patent No. 6,727,092 to Shah et al. ("Shah"). Because EP '484 only teaches dodecylammonium, Shah is cited for teaching dodecylammonium *bromide* for removing the lipid envelope of HCV. Shah does not remedy the many other defects of EP '484, however. For this reason, the combination of EP '484 and Shah does not render obvious claim 7.

**V. Request for Interview**

If the Examiner declines to allow the claims, Applicant requests an interview.

**CONCLUSION**

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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